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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,421	11/21/2003	John Eric Peckham	S63.2-11294-US01	3394

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VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER	
CHENG, JACQUELINE	
ART UNIT	PAPER NUMBER
3768	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/719,421	PECKHAM, JOHN ERIC	
	Examiner	Art Unit	
	Jacqueline Cheng	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant has supplied the missing drawing so therefore the objection to the drawings has been withdrawn.

2. Applicant's arguments filed October 10, 2006 in respect to claims 28-35 have been fully considered but they are not persuasive. The examiner respectfully disagrees with the applicant's argument about **claims 28-33** that the apparatus as claimed is not found in Stinson (US 6,340,367 B1) and Thompson (US 5921,978). Thompson discloses several embodiments wherein the medical device of a catheter discloses a first and second marker strip, both being parallel to the longitudinal axis of the medical device. The embodiment that shows it best is the embodiment in fig. 38 and 39. In this embodiment the two markers are of different size, one being larger than the other (col. 10 line 40-51). The larger marker would be more visible as it has more area than the smaller marker. As well as being more visible because of size, it would be obvious to one skilled in the art to make these two markers of two different materials that would make one marker appear darker than the other marker on the image, as is done in the embodiment that is in fig. 6 and 7. In fig 6 and 7 the two different marker halves are made of two different materials such as stainless steel and platinum so that one of the markers is more visible because of darkness (col. 5 line 2-10, col. 5 line 28-40).

3. As to the combination with Stinson, it would be obvious to combine Thompson with Stinson as the overall idea that a marker is a marker and so to use the reasoning of Thompson to use different sizes, or different materials for the two markers would be an obvious change.

Stinson actually already does disclose that various combinations of the radiopaque marker are possible including multiple markers or wires. So therefore it would be obvious to combine the teachings of Thompson with Stinson to have a stent device comprising the two markers running parallel to the longitudinal axis (fig. 5 elements 14, col. 7 line 17-19), and have these markers be of different radiopacity.

4. Directing the attention to **claims 34 and 35**, the examiner respectfully disagrees with the applicant's argument that there is no motivation to modify the Clement device to arrive at the device that meets the limitations of the rejected claims. The Clement device is a rotational ablation device that also has a lumen and a port that carries away bodily material (col. 3 line 26-37). This medical device also comprises a radiopaque marker at the end of the catheter (col. 4 line 56-58). Clement does not explicitly disclose the particulars of this marker, so it would be obvious to one skilled in the art to use any known orientation of markers such as disclosed in Thompson. Placing the markers of Thompson on the catheter of Clement would also further the utility of Clement to be able to have better control over the steering of the catheter and determining the location and rotation of the catheter tip.

5. Applicant's arguments with respect to **claims 1-27** have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-12, 14-27, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 5,203,777) in view of Skujins (US 7,153,277 B2).

8. **Claims 1-12, 14, 24-27, 36, 37:** Lee discloses a medical device and a radiopaque marker that is permanently coupled to a medical device, which can be any known medical device in the art such as a catheter, an ultrasound device, a cannula, or basically any device that has a body which is tubular in form and has a distal end and outer periphery, of which a catheter sheath, stent of any form, and an expansion balloon fall under. This marker is a radiopaque marking system used to determine the rotational position of the medical device using an imaging device when the medical device is positioned within a body lumen. The markers are viewed in an image and then the medical device is positioned in the desired orientation. Lee discloses that the markers are rectangular in shape, and be made from a suitable conventional metal or the like (abstract, col. 3 line 46-52, col. 5 line 5-10). Although Lee does not explicitly disclose that this metal is shaped into a wire, it is obvious to one skilled in the art to use wires as the marker on a medical device. This can be seen in Skujins, who teaches the uses of radiopaque metal markers in the shape of wires (col. 6 line 35-45, col. 6 line 59-col. 7 line 2). So if wire was chosen to be used as the marker material of Lee, it would mark the boundary of the enclosed rectangle (creating a loop), having a first portion that extends in a circumferential direction, a second portion that extends in a direction parallel to the longitudinal axis, a third portion extending in a circumferential direction again, and a fourth second extending in a direction along the longitudinal axis (fig 2).

9. **Claims 15-23:** Lee discloses that other variations of markers besides a substantially square marker can be used. An example that Lee gives is using directional indicators which forms a symbol of an "E", which has a first portion in a circumferential direction and a second portion in a direction parallel to the longitudinal axis and provides directional indicators in a form direction non-parallel to the longitudinal axis (the first and second (and a third) directional indicators that form a symbol being the stems of the E). Also although Lee does not explicitly disclose an example of a marker as being an arrow, it is well within the boundaries of one skilled in the art to use an arrow marker, as it shows direction and also would be able to show rotational orientation. As to the symbol being viewable over a rotational range of 35 degrees or less, as you can see in fig. 4 as the catheter is being rotated 45 degrees from the 0 degree position the marker 60, which in a different embodiment could be the E or an arrow symbol can is still viewable.

10. **Claims 13** rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Skujins further in view of Pacetti (US 6,574,497 B1). Although Lee discloses that the marker coupled to the medical devices is a radiopaque marker it would be obvious to one skilled in the art at the time the invention was made to use a marker that would viewable in whichever type of imaging device is being used. In a case where using an x-ray imaging device is not ideal, an MRI device can be used. In such a case the marker would have to be an MRI marker. Pacetti discloses such a case wherein x-ray fluoroscopy is the preferred imaging modality for procedures such as cardiovascular procedures, but it may not be ideal for various reasons such as the ionizing x-rays are dangerous, so may not be ideal for patients who has repeated interventions. In such a case

using an MRI device and MRI markers would be much more ideal (col. 1 line 13-39, col. 3 line 3-60.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700